Lawrence, Susan

From: Tomasino, Stephen
Sent: Tuesday, November 03, 2015 6:58 AM
To: Lawrence, Susan
Subject: FW: Comments on the New Evaluation of Bactericidal Activity of Hard, Non-porous Copper/Copper-Allow Surface Protocol

Another set embedded in email...

From: Perry, Mark
Sent: Friday, January 30, 2015 2:23 PM
To: Tomasino, Stephen <Tomasino.Stephen@epa.gov>
Subject: FW: Comments on the New Evaluation of Bactericidal Activity of Hard, Non-porous Copper/Copper-Allow Surface Protocol

From: Diego Ugarte [mailto:Diego@antimicrobialtestlabs.com]
Sent: Tuesday, January 27, 2015 3:39 PM
To: Perry, Mark
Subject: RE: Comments on the New Evaluation of Bactericidal Activity of Hard, Non-porous Copper/Copper-Allow Surface Protocol

Good afternoon Mr. Perry,

On behalf of Antimicrobial Test Laboratories, we are pleased to submit the following public comments and questions regarding the proposed "Protocol for the Evaluation of Bactericidal Activity of Hard, Non-Porous Copper/Copper-Alloy Surfaces."

Overall, we can all agree that this is a complete overhaul of the current method, not only in time but also in difficulty and practicality from a lab perspective, which will directly influence cost. Due to the excessive cycle requirements, there doesn't seem to be a cost effective way of screening materials thus reducing the pool of potential registrants.

Abrasion and Chemical Exposure:

At first glance, the use of a scouring pad seems excessive and how does this relates to "normal" wiping and or surface cleaning? Keeping with historical wipers (TX wipes) would, at a minimum, maintain consistency among similar methods or approved protocols requiring abrasion.

Chemical Treatment and Time:

What is the rationale behind the high active concentrations and use of all three? Can a registrant define the product that is to be used for cleaning or disinfection/sanitization? If incompatible with the three chemicals listed in the method but compatible with an alternative (Quat, HOCL, ClO2, etc), does this rule out chances of registration?

What is the rationale behind only 3 chemical abrasions per day, or 12 weeks. This will likely require chemical preparation daily, and especially bleach, which requires additional time, thus money. At first glance it looks like any lab would be able to fit in 10-20, possibly more, depending on the wait time between abrasions, currently at 2 hours. What is the rationale behind such a long wait time? If rinsed with water after treatment, why can't the subsequent treatment begin within 10 minutes or after visually dry. Can this be accelerated via increased temp or elevated temp exposure between cycles to reduce the overall number of cycles. What is the rational behind 180 abrasions?

Claim:

What happens if someone makes it to 179 abrasions and performance is demonstrated? Is there or will there be a standard for comparative purposes or will reduced abrasion cycles warrant reduced claim language?

The chemical abrasions are more robust than any procedure that has crossed ATL in the past that involves potential residual or continuous claims. Will this be addressed in future drafts?

We look forward to hearing your comments and please let us know if you have any questions.

Best Regards,

Diego
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Diego Ugarte, B.S.
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http://www.AntimicrobialTestLabs.com

To Mark Perry,

This is a comment on the posted Protocol for the Evaluation of Bactericidal Activity of Hard, Non-porous Copper/Copper-Alloy Surfaces (9/19/14), from Mary K. Bruch. I am a member and secretary for ASTM Subcommittee on Antimicrobial and Antiviral Agents (E35.15). I worked on the Subcommittee Task Group for the development of ASTM Standard Test Methods for these surface-active copper products over several years. I also joined the ASTM Copper Committee after the Methods were transferred to it.

This EPA Method is a significant advance in testing these products. I have raised some questions about wording and made some editorial corrections.

Mary K Bruch

General Comment: terms and definitions

1. Surface Products -- Is the term surface products or product surfaces? The antimicrobial activity maybe throughout the material or applied onto a coating of the surface (silver products and copper plating). Is there a surface product? I understand that the antimicrobial activity is being measured at the surface.

Test Carriers: exposed and unexposed

The test carriers for antimicrobial testing will be ones subjected to physical abrasion and chemical erosion by extensive pre-treatments that are intended to simulate in-use exposure of copper or copper alloy surfaces.

The protocol title involves the "Evaluation of Bactericidal Activity." I believe there is some confusion in using "exposed" and "unexposed" to indicate chemical and physical treatment of the carriers that will be used for testing bactericidal activity. Could you use pre-treated and untreated carriers? The exposed terminology has a long history with using bacterial contamination.

This pretreating of the carriers incorporated into a single test of that bactericidal action is a good step. If this terminology is retained, an explicit definition of the terms must be included.

1. Overview – Do you mean "copper alloy –based product surfaces?"

1st bullet – line 2 as it relates

2nd par. line 2 – product surfaces

line 6 – product surfaces

line 8 – product surfaces

3rd par. Is assessment the appropriate term? Stressing or an another word , assessment is not the right term. Clarify exposed carriers.

Line 2 – comma after term,

II Product Characterization

line 5, delete comma after material.

Cannot say product proposed that. Do you mean the label proposes?

3. Use or instead of slash since it can be read or or and.

III Abrasion and Chemical Exposure Overview.

Add a hyphen after Exposure in the title or put Overview first.

3. Conducting the Chemical Solution Treatment

1st bullet – inside a Petri Plate?

3rd and 4th bullet – no s on abbreviation of minutes.

IV Test Methodology

A. Carriers – line 7 – as closely as possible.

2. ensure not insure

3. physically screened used here – means what? Does this mean stainless steel control carriers?

4. universal correction – delete s on mins. Again, use of Petri dish?

5. What is lip of Petri plate? Top? Top is ajar? Explain.

If you use 70 percent ethanol to decontaminate (or perhaps a better choice – 95 – 98 percent isopropyl) there will possibly be spores surviving this treatment.

5. A single cupon incubated as a sterility control tells you nothing about the condition of the rest of the lot that was decontaminated, not sterilized. Refer to the sampling required to determine sterility.

B Test Cultures

2. line 5 Alternative not alternate

2b. Is the meaning interior edges or interior surfaces?

Comment: Should the user of this method have to go the Use Dilution Methods to find culture techniques? Perhaps an addendum or appendix to the method describing these culture procedures would help those without ready access to the UDM.

3. line 4-5 phosphate buffered saline no caps). The names of media are not capitalized unless they are commercial products.

D Efficacy Test Procedure

2 . control carriers should be performed. Replace performed with another word, tested? Can't perform carriers.

5. line 3 no s on abbreviation for seconds.

E Study Controls

1. Purity Control - should be Pure Culture Control. This is not a very precise method to determine a pure culture.

5. define numbers control.

6. This study is what? Explain <_50% criterion?

G. Product Performance Data

1st bullet Is magnification used to identify effects of chemicals or abrasions?

3rd bullet: 0.5 log – no s.

Line 1, parenthetical statement.

Spell out meaning of slash. Is it "and" or "or?"

Product Efficacy – line 2 – Should this be number and not numbers?

1A label claims: 1. 1 – hour contact